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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/890,219

12/12/2001

Hiroharu Matsuoka

MATSUOKA=18

7465

1444

7590

09/13/2004

BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/890,219

**Applicant(s)**

MATSUOKA ET AL.

**Examiner**

Binta M Robinson

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 and 28-34 is/are pending in the application.  
4a) Of the above claim(s) 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/18/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **Detailed Action**

The applicant's election of group I and the example 102 on page 264 is acknowledged. The applicant traverses the restriction alleging that the PTO has not demonstrated that the compounds do not possess a technical feature over the art. However, the compound of formula I has many variables and does not share a common core. Additionally, 2 art references have been found which are obvious over the claimed invention, so the instant invention does not have a special technical feature over the prior art. There is unity of invention between the compounds of formula I found in claim 1 and the intermediate found in claim 30 because the intermediate and final products share the same basic essential structure and the final product is directly manufactured from the intermediate. See Rule 13.2 So the restriction requirement is revised so that claim 30 will also be examined in Group I. The radicals R8, R9, R20, R10, R12, and Y for the intermediate of (6) are as defined in claim 1, P is H or a protecting group of amine, and R11" can be any of the moieties except optionally substituted heterocyclic ring, claimed in the claims dated 6/18/2004, However, there is a lack of unity of invention between the compounds of formula I in claim 1 and the intermediates found in claims 31-34 because the intermediate and the final products do not have the same essential basic structural element. The restriction is revised to take into account the preliminary amendment as well, so that the claims to be examined in Group I are – claims 1-25, 28-30. Claims 31-34 are withdrawn from examination as well as the unelected portions of claims 1-25 and 28-30.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to

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prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25, 28-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 19, 20 of U.S. Patent No. 6586630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Patent teaches a subgenus of the instant genus of compounds.

U.S. Patent No. 6586630 teaches the instant compound as shown in Formula I, R1 is an optionally substituted phenyl group, R2 is a hydrogen, R3 is a hydrogen, an optionally substituted straight chained or branched alkyl group having 1-3 carbon atoms, an optionally substituted amino group or a hydroxyl group, R4 is a hydrogen atom, a methyl group or an ethyl group, R5 is an optionally substituted straight-chained or branched alkyl group having 1-6 carbon atoms, a cycloalkyl group having 3-7 carbon atoms or an optionally substituted phenyl group, R6 is a hydrogen atom, a methyl group or an ethyl group, R7 is a hydrogen atom, an optionally substituted straight-chained or branched alkyl group having 1-3 carbon atoms or -CO-N(R9)R10; R8 is of the general formula 2, R9 and R10 which may be the same or different, each represent a hydrogen

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atom or an optionally substituted straight-chained or branched alkyl group having 1-3 carbon atoms, E11 is a hydroxyl group, R12, when R11 is a hydroxyl group, represents a substituted straight—chained or branched alkyl group having 1-6 carbon atoms, a substituted straight-chained or branched alkenyl group having 2-6 carbon atoms, substituted straight-chained or branched alkynyl group having 2-6 carbon atoms, X is a carbonyl group, Y is a carbonyl group. At columns 54-55, see the compound of formula 1. The difference between the prior art compound and the instantly claimed compounds is the teaching of a subgenus of the instant genus. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For instance, see the compound, 14 at Table A-4, column 15, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24, 25, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 24, page 3 of the preliminary amendment, line 1, the term “medicine” is indefinite because it is not a statutory class of invention. There is also no reference to an inert, pharmaceutically acceptable carrier.

B. On page 4 of the preliminary amendment, Claim 25 is indefinite because it does

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not make reference to an inert, pharmaceutically acceptable carrier.

C. In claim 30, line 4, the phrase "are as defined in claim 1" is indefinite because this claim is an independent claim drawn to an intermediate compound, yet it's radicals are defined in claim 1. The radicals R8, R9, R20, R10, R12, R13 and Y must be defined at the claim.

The IDS filed 6/18/2002 has been considered.

The elected species is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

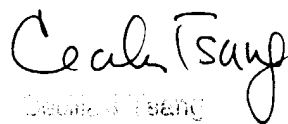
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



BMR  
September 7, 2004



Cecilia Tsang  
Supervisory Patent Examiner  
Technology Center 1600

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